Technical Support Section Efficacy Review - I Antimicrobial Program Branch

D IN 03-26-90	OUT 04-11-90
Reviewed by Bruce H. Mann 4	24 90 Date 04/11/90
EPA Reg. No. or File Symbol	211-36
EPA Petition or EUP No.	None
Date Division Received (02-20-90)
Type Product(s): Hospital D	isinfectant
Data Accession No(s)	414161-01
Product Mgr. No. PM-32 (Francis)
Product Name(s) T	ri-Cen
THE RESERVE TO THE RE	
Comp., Name(s) Central	Solutions, Inc.,
Submission Purpose Amendm	ent to support virucidal claim vs. HIV-1
(AIDs Viruse) with d	ata and label.
Type Formulation Liquid conc	entrate to be diluted for use
Active Ingredient(s):	
Sodium ortho-benzyl-para-chlor	phenate 4.40
	2.82
Sodium para-tertiary-amylphena	te 2.49

200.0 Introduction

- 200.1 Use(s): Refer to the last accepted label dated 09-20-89, and see the most recent proposed label dated 10-30-89.
- 200.2 Current Submission: The current submission consists of data intended to support efficacy of the product as virucidal against HIV-1 (AIDS virus) and to add a label claim to include efficacy against HIV.

 The current submission data reports and label are summarized below.

201.0 Data Summary

201.1 Brief Description of Tests (MRID 414161-01)

"Virucidal Efficacy Tri-Cen Hospital Disinfectant "EPA REG NO 211-36" SRI Project No. 6996 by Bonnie J. Bowdon, Southern Research Institute, P. O. Box 55305, Birmingham, AL 35255-5305. The reports are dated January 08, 1990. Reports prepared for Central Solutions, Inc., Kansas City, Kansas 66115.

201.2 Test Summaries

- 1. Method: EPA Product Performance Guidelines, Subdivision G: Product Performance, 1982, (Section 91-30, pp. 72-76). and the specifics in the Southern Research Institute test protocol approved by EETMS Efficacy, APB, RD, dated 08-15-89.
- 2. Test Virus: Human immunodeficiency virus Type 1(HTLV-IIIB strain).
- 3. Virus Inoculum & Drying Procedure: Two-tenths ml of virus pool in RPMI-1640, containing 5% heat-inactivated fetal calf serum, was dried on the bottom surface of glass dishes (28 cm² area) at approx., 23⁰C until visibly dry(approx. 45 minutes), and then incubated in 35-37⁰C in a dry oven for an additional 30 minutes for dryness.
- 4. Exposure: Total time of 10 minutes(approx. 0.2 ml was sprayed until wet and allowed to remain in contact with disinfectant. After 10 minutes of exposure, an aliquot of the virus /disinfectant mixture was added to a Sephadex column for separation of virus from disinfectant.
- 5. Sephadex Gel Filtration:
 As/per the attached materials and methods for 3 minutes to clear the void volume, 0.6ml of virus/disfectant mixture was loaded on column, filtrates, collected and diluted ten-fold for assay of virus.
- 6. Test Samples: Lot/batch 058924 and lot/batch 68923. Sample Rec'd 11-01-89. Tested 12-06-89. Completed: 12-13-89. (Formulation NO. RD -148B0689)
- 7. Use Dilution: Diluted product 1:128.
- 8. Infectivity Assays: Polybrene-treated(2 ug/ml) MT2-cells were inoculated and incubated for 7 days at 37°C for virus infection. ion. Primary detection of virus scored by lytic cytopathic effect (CPE) after 7 days of inncubation at 37°C.

Refer to infectivity assays under the attached materials/methods.

10. Results:

Disinfectan	t Exposure	Organic	Hard	ID-50/LD50	
Test Temperature	<u>Time</u>	<u>soil</u>	<u>Water</u>	058924	068923
Sample			•		
Virus NA Control	NA	5% Serum	NA	5.00	5.00
Virus + 230C Non-Virucidal (RT) Disinfectant	10 minutes	5% serum	NA	4.50	4.67
Virus + NA Disinfectant	10 minutes	5% serum	NA	<u><</u> 0.5	<u> <</u> 0.5
Toxicity NA Control	NA	NA	NA	< 0.5	< 0.5
Log 23 ⁰ C Reduction	10 Minutes	5% serum	NA	<u>></u> 4.50	<u>></u> 4.50

NA= Not applicable.

^{11.} Conclusions: The data meet the requirements for demonstrating virucidal efficacy of the product against HIV-1 in the presence of a moderate amount of 5% organic soil (blood serum) when used at a dilution of 1:128 for a contact time of 10 minutes at room temperature (230C) and in deonized water.

Part II Antimicrobial Program Branch/EETMS

EPA Reg. No. or File Sym	bol 211-36	
Date Division Received _	(03-26-90)	
Data Accession No(s)	414161-01	
Product Mqr. No	PM-32 (Francis)	
Product Name(s)	Tri-Cen	
Company Name Central	Solution Inc.,	

202.0 Recommendations

202.1 Efficacy Supported by the Data

The submitted data meet the requirements to support effectiveness of the product against HIV-1 (AIDS virus) on hard, non-porous surfaces in the presence of a moderate amount of 5% serum when used at a 1:128 dilution for a contact time of 10 minutes at room temperature (23 $^{\circ}$ C).

203.0 Labeling

The comments are applicable for the proposed label addition for "Tri-Cen Hospital disinfectant" submitted and dated February 20, 1990.

The submitted label does not contain any adverse comments, however, when the proposed label addition is added to the full label, the label claim for HIV-1 (AIDs virus) must be reflected under the directions for use as indicated on the attached "Label Requirements For Antimicrobial Pesticides Used On Hard Surfaces Against HIV-1 (AIDS VIRUS).